IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
STATESVILLE DIVISION

RAMONA WINEBARGER and REX WINEBARGER,
Plaintiffs,

CASE NOS. 5:15CV57-RLV; 3:15CV211-RLV

v.
BOSTON SCIENTIFIC CORPORATION,
Defendant

MARTHA CARLSON,
Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION
Defendants

PLAINTIFFS OBJECTIONS AND COUNTER DESIGNATIONS TO DEFENDANT BOSTON SCIENTIFIC'S DEPOSITION DESIGNATIONS OF ROGER GOLDBERG TAKEN DECEMBER 13, 2013

BSC Designations	Objection	Plaintiffs Counter Designation
rg121313, (Pages 413:20 to 440:15) *** 6 Q. So how did your treatment practice 7 then evolve to a point when you began to use 8 additional tools like the term Capio? And 9 give the jury some sense for what a Capio is 10 and why that was, in your mind, an innovation 11 that was useful in the treatment of pelvic 12 organ prolapse. 13 A. Well, so Capio was a device that I 14 actually had seen in my residency. 15 First and foremost, what Capio 16 allowed us to do was a much, much smaller 17 dissection, much less trauma to the tissues, to 18 do what we call a sacrospinous suspension, 19 which is a core procedure. For any 20 urogynecologist like myself, to do a vaginal 21 suspension many of us rely on the sacrospinous.		*Counter Designation to 424:6 - 435:17* *rg121313, (Pages 492:2 to 495:18)* *492* *2 Q. Now, you had also talked about the* *3 Capio system as being a very effective and* *4 safe tool versus the older trocar system;* *5 right?* *6 A. Correct.* *7 Q. Truth of the matter is Boston* *8 Scientific has had quite a bit of problems* *9 with Capio; haven't they?* *10 A. That's not*

In the old days we used to have to use retractors. And it would actually be kind of a long operation, tough visualization,

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we'd use large deep retractors to expose the ligament visually.

So with Capio, and we were a part of this to help, you know, sort of push the best technique along with the Capio, we started to develop techniques that involved very, very small dissection, placement of the stitches without the retractors. And that translated into a quicker operation, less blood loss, just a much more elegant repair.

So for this so-called sacrospinous suspension, it was this gem of a device.

Q. And you have a Capio there. Why don't you show that for the video camera.

A. So this is the Capio device. And if you've never seen, obviously it might not make much sense, but it's actually quite simple.

The goal here is instead of, again, using a standard stitch technique deep in the body, we'd have to use long suturing instruments. Here, we can slide the device up, place it against the ligament -- and obviously

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I don't have this loaded with a suture. But it's a single press. And if you look carefully, I don't know if you can see it against my hand, there's a catch mechanism.

Q. Okay.

A. And so it basically places a suture with a very controlled depth. It'll never go deeper than this. We developed, again, a technique that was real quick and efficient for sacrospinous.

Q. Okay. So how did you use the Capio initially with something called biologic and then how did you evolve into polyform mesh and then evolve into the idea of the Uphold? Explain that for the jury's benefit.

A. Yes, so that's exactly right. So we had developed, around 2000, we published on this actually, the anterior approach to the sacrospinous, using the Capio was sort of a watershed transition.

anything that I'm aware of, no. I mean I've used Capio for over a decade and it's been a part of our practice. I don't know of any, I don't know of any inherent risk to the device, period. It's a suturing device.

Q. You hadn't had any malfunctions with Capio?

A. Device malfunctions?

Q. Yes.

A. If it's an issue of the needle not catching or a, you know, reported device malfunction, that's a different story and you'd have to ask BSC. But risk? That doesn't pose a

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risk to the patient.

(Deposition Exhibit Number 840 was marked for identification.)

BY MR. PIRTLE:

Q. Well, let me show you Exhibit 840.

(Document tendered to the witness.)

We simply sampled the Boston Scientific complaints database just for the year beginning in 2010, just for the year starting in 2010.

Have you ever seen this database?

A. No.

Q. For the year beginning 2010, this is what the database from Boston Scientific --

Without getting too technical, this was apparently a much improved approach to the sacrospinous ligament deep in the pelvic area resulting in a better anatomic outcome

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than what had been taught in the textbook for many decades.

So on the heels of that, to answer your question, we then started to ask ourselves well, we have this really elegant fixation method, how can we start to tackle the cystocele. We keep seeing these cystoceles come back.

Q. And cystocele is the bladder?

A. That's the dropping of that anterior vaginal wall which provides a platform of support for the bladder.

So a woman will see a balloon of tissue coming out --

Q. Coming out of the vagina?

A. Coming out. And what she's seeing is actually the vaginal skin. But right behind that is the actual organ of the bladder. You don't see the bladder, but you're seeing the vaginal wall collapse underneath it.

So to elevate it in a way that would actually hold up durably in a reliable fashion, we started to ask can we begin to use

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this technique not only to suspend the top of the vagina to the sacrospinous but can we incorporate something to reinforce the cystocele.

And that, to answer your question, is where we got into the incorporation of biological grafts.

Q. And what's a biological graft?

A. So a biological graft, similar to how you have a skin graft put on a defect in the skin, these are biological products. They either come from human tissue or animal tissue.

Q. Okay.

A. In some cases they're actually autologous where they're harvested from the patient's own skin. I've never done that technique. But I for several years used an off-the-shelf product called Repliform --

Q. Okay.

you said ask them -- says.

On the left there's complaint numbers; right? Do you see a list on top?

A. Yes, I do, I do. I'm following.

Q. And then there's a date when the complaint was entered; right?

A. Okay.

Q. And then there is a Priority and it says Malfunction starting on the top of the

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third column and going down; right?

A. Yes.

Q. And then there is an MDR ID number; right?

A. Right.

Q. And then it goes on to lot and batch numbers.

If you look down this page -- and there's several pages. I'm going to say this is a spreadsheet. So we had to print it out in a different form. But down this page there's Malfunction, Malfunction, Malfunction, some of them are double entries.

But then here on 2/2/10, there's a listing for serious injuries; right? That particular serious injury was associated with the Pinnacle. These others were associated with the Pinnacle. See all these over here for the Uphold; right?

A. -- which was just a very, very well tolerated, been used for years in various degrees, various areas of surgery, had an excellent tolerability profile.

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We actually incorporated Repliform into a Capio-based technique that started to move the needle fairly dramatically actually. Our cystocele recurrence rates which at our center had historically been around 42 percent actually started to decline by I think around 68 percent, drop in failures.

Q. Okay.

A. So that was very encouraging. And we started to in a sense gain a reputation for having, you know, developed this anterior apical new method.

Q. Okay. And then you transitioned to using a mesh. Explain that to the jury.

A. Well, so as the, you know, as the -- as mesh was becoming part of the discussion in surgery, you know, we started to ask ourselves, you know, the outcomes would certainly indicate that mesh can provide certainly a better anterior outcome. And even to this day, there's really uniformity that the randomized trials have shown that in terms of sheer anterior compartment support, you can get a phenomenally strong repair. We started

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to ask can we incorporate a very simplified approach, you know, again, building on what we had done with Capio, leveraging what we had learned with Repliform and the biological graft, can we use the unique properties of mesh to actually reduce our fixation points.

Because of the inherent bonding properties of mesh, you know, we could potentially do a lot less fixation, perhaps have less pain for the patient, and a quicker, simpler operation, which, you know, years later did eventually come to fruition.

Q. How did you go from that intermediary step then to the device that the jury may be hearing about called the Uphold?

A. So Uphold was -- so we were in our center, again, evolving from biological grafts to a mesh that we were cutting ourselves and having to stitch in.

Q. Okay.

A. I'm following.

Q. And then of course there's several pages of that we can go through and point them out but I won't keep you here.

Then the next page is actually

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the continuation -- if you go to 162 on the Bates number, there's a continuation of the database. If this was spread out, they would be attached. And there's a description of the malfunction in more detail.

See that?

A. Yes.

Q. And then there are several pages following showing the problems that doctors, your colleagues, have experienced and reported to Boston Scientific.

You've never seen this database before right now?

A. No.

Q. You wouldn't know how big it is; do you? Right?

A. As I said, I haven't seen this until now.

A. And the sutures themselves tend to, with any surgery, cause pain, and also involve a lot of adjustment, fine-tuning, which is difficult, it's difficult to teach 431 and it's difficult to do. So Uphold was a true merge. And perhaps there was a lucky timing involved. But the technology that was being introduced to Boston Scientific's line called the mesh leg or the mesh arm which was incorporated into the Capio needle -- and Dr. Miller had contributed this technology -- came at the perfect time for all of us to realize, you know, boy, we can eliminate the suture tie-downs, we can make this operation even simpler. And so it was a collaboration of these two ideas into one. Q. So if you assume and assume with me that the Uphold would have received clearance from the FDA in late 2008, was there a time prior to that where you were having your own clinical experience with a device that essentially was the equivalent of the Uphold? And describe that for me. A. Well, yes, I mean and to varying degrees. And in the end actually, pre Uphold, we had experience with cutting down the Pinnacle device to the specs that we felt were going to be Uphold. 432 Moving from that point in time actually a little bit further back, we had been cutting polyform mesh to sort of convince ourselves what's the best configuration here. So there was a period of time where we were self-shaping polyform and Pinnacle mesh to match the specs of what eventually became Uphold. Q. And you have with you I believe an example of the Uphold. If you could hold that up. So just describe what the various components of that are. A. So I should have loaded this a minute ago because I'll show you right now. Let me show first the implant. The actual implant is what you see here, the blue. It's very small. So this is the implant size. It has a top edge which fixes onto the top of the cystocele. This little curvature on the	431:13-432:8 FRE 401, 402, 403 Impermissible FDA reference 432:9-433:10 FRE 403 On information and belief, blue mesh describes Uphold Light which is not the product at issue.	

bottom actually is designed to secure either onto the cervix, to fix onto the cervix, which would go right there, or to the apex of the

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vagina if a woman has had a hysterectomy before. These arms actually are what fixes the mesh into place. And to show you this, let me just load it up.

It's very simple engineering which I think is always, my feeling is simple is always good when it comes to surgery.

So the Capio needle loads into the device. It just pulls back into place. So the needle is now set in the device.

Q. Okay.

A. And I don't know if it'll go through a napkin -- I've never tried this as a demonstration but it probably will. So if that's the ligament, say deep into the body, you place a suture -- this is an ordinary suture, no bigger than any other suture caliber we've used for years with Capio.

This is called a dilator tube. All the dilator tube does is as it passes through this ligament tissue creates just enough wiggle room, just that extra millimeter or two, to allow for passage of this component.

And this is a sleeve which you

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will see in a moment this is all going to be removed. The only implant left behind is the mesh. Just to show you how it goes through the ligament, it'll pull through. Obviously this is a napkin, so it's a bit challenging.

Whereas normally in years past we would have had to suture this down, this mesh will now self-affix into place. Now, it doesn't pass through and through the muscle. It's actually just making sort of a hairpin turn in a very, very defined small space.

Q. And what about the rest of the arm there, what happens to that?

A. This all comes off. I could do that if we had a pair of scissors or something to cut with.

Q. That's okay. I think we want to keep that intact, if we can.

A. Essentially this plastic, everything is removed except -- with the exception of the implant, which this implant will not only suspend the cervix or top of the

vagina but also this main body of the implant sits underneath the cystocele. And the

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combination of the --

Q. The cystocele meaning the bladder?

A. The dropped bladder, the dropped vaginal wall.

Q. Okay.

A. This provides that reinforcement to that critical area which was at the highest rate of recurrence. And this implant unchanged from its original design has reduced our risk of cystocele recurrence literally by about 95 percent.

So the number of women who have recurred after this to date with very careful follow-up, we always say we never know what's going to happen tomorrow, but it's truly changed the reality for these cystocele outcomes.

Q. Okay. How does the size of the Uphold compare to earlier generations of the transvaginal mesh products for pelvic organ prolapse? And you brought some.

A. I did.

Q. And let me, for the jury's benefit, let me mark as Exhibit 827 the Uphold

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and let me mark as 828 the Capio. And we'll have to figure out a more elegant way of preserving those.

(Deposition Exhibit Number 827 and Exhibit Number 828 were marked for identification.)

BY MR. KEENAN:

Q. What did you bring here and hold it up to the jury?

A. So this is a Prolift. Full disclosure, I've never used the device. This is something that I was able to get through training.

Q. Who makes the Prolift? Not Boston Scientific?

A. No. This is Ethicon. So this was one of the quote unquote first generation lift kits that came onto the market using a trocar system.

So the Prolift -- I would be unable to give a great demonstration of how this goes in. But I can show you the basic

elements are, you know, just fundamentally different, which it does not take a pelvic surgeon to see. So going back to the Uphold implant, this is it. I mean I have a small hand, it's in the palm of my hand, and this is the total Prolift mesh. This is just what it is. There are anterior and posterior components. There are, as you can see, arms that are designed to go through the gluteus muscles, the levator muscles, and the obturator muscles. And by "going through," what I mean is unlike the Capio where these arms of mesh just pass into the tissue a small degree and hitch on, these are arms that were actually designed to go from inside the vagina out to literally the external skin. How do we do that? Well, the technique was using a long needle, and this is what we call a trocar-based kit where basically this needle, believe it or not, would pass from an external incision, like near the buttocks, and the doctor would then fish this needle out through the vagina. Albeit certainly was used successfully by a lot of good doctors out there, this you can see is just a very, very different mesh size and delivery system. These are the tubes that are used for the device just to facilitate the mesh placement. Q. Okay. Why don't you put that -- we'll collectively mark that as Exhibit 829. (Deposition Exhibit Number 829 was marked for identification.) MR. KEENAN: Why don't you put that back in the box. BY MR. KEENAN: Q. And then you brought another device made by another company. Just describe briefly what that is. A. Sure. This is Bard. And, again, I've never used this, so I can't give you an intimate introduction to it. But this is more of an isolated anterior compartment repair that Bard was -- Q. What's the name of this device?	436:8-438:13 FRE 403 Confusing and Misleading. The Prolift total treats posterior and anterior prolapse	*[Counter Designation to 438:14-440:15; 442:14 to 444:21 from Deposition of Roger Goldberg, MD taken January 9, 2015* *rg010915, (Pages 128:23 to 129:20)* *128* *Q. You do utilize slings?* *A. Yes.* *129* *Q. Do you utilize slings that are inserted or the procedure involves the use of trocars?* *A. Yes.*

A. This is Avaulta. So this is Avaulta. It was designed as a four-arm 439 system, you know, with these arms going into the side wall muscles. So a through and through passage with needles. Similar in delivery system concept to the Prolift but obviously a somewhat scaled-down implant for single compartment use. Q. But also using the trocars as distinct from the Capio? A. Exactly. So the trocar -- just to show -- this is just a different shape. This is, again this is designed for passage from the external skin into the vagina. So inherently a different concept than a direct suturing technique using the Capio device. Q. Okay, okay. MR. KEENAN: Let's mark that collectively Exhibit 830. (Deposition Exhibit Number 830 was marked for identification.) BY MR. KEENAN: Q. And I think the jury understands this, but just so we're clear, you have no clinical experience with either of those two 440 trocar-based delivery systems. A. That's right. I literally never used one of them. Q. And why is that? A. I guess it's a funny way of putting it, but I grew up on the Capio. Again, I happened to train in the Capio fixation methods and actually early on started to innovate simpler ways of using the Capio. So by the time the trocar products entered the market, it was not even an afterthought to begin passing needles from outside to in. We knew very efficient ways of getting suture graft or mesh into place with a simple vaginal incision.		*Q. So, you personally are involved in the implantation of polypropylene mesh slings that does involve the use of trocars?* *A. Yes.* *Q. The slings, what slings do you use?* *A. Advantage Fit, TVT. I've used the Bard product, the Align, Obtryx.* *Q. So, you named for me everything was retropubic until you got to Obtryx.* *A. Yes, and Monarch.* *Q. Let me ask you this: For the slings that you utilize, can you agree that the anchoring points that is for the lateral pull with the trocars is through membranes and muscle?* *A. Yes, laterally.* *Q. Laterally, correct?* *A. Yes.*
rg121313, (Pages 445:9 to 452:14) 445 Q. On the next page you talk about the no overlapping suture line. And I'll just read it here. "Thus far in our experience, it appears the rate of vaginal mesh erosion associated with our repairs is favorable as	445:9-447:3 FRE 401; 402; 403 Incisional approach is irrelevant because neither	*[Counter Designations to 445:9-447:3 from the Deposition of Roger Goldberg, MD taken January 9, 2015]* *rg010915, (Page 83:1 to 83:21)*

there is no overlapping of the mesh implant and the suture line." Do you see that? A. Yes, I do. Q. Explain to the jury how that was built into the design of the Uphold. A. Well, frankly this was about I think 30 cases into our Uphold experience. And I remember the day that we were operating, we realized gosh, why are we making a vertical incision, why not, you know, as with other 446 vaginal procedures we do, why not configure that incision to avoid overlap with the mesh. Q. And when you say "overlap with the mesh," just explain what you mean. A. Well, so at the end of the -- this would be a very crude rendering -- but if you look at the Uphold as an implant, I'll show it alone here, this is something we drew before for a different reason. But at the end of the day you either have to make an incision in the vagina that is closed in a configuration that's directly overlying the mesh, which we had done initially with very good success, we didn't have many exposures at all. But it was the sort of "aha" moment where why don't we just put our incision a few millimeters going this way above the mesh, so when we close it your stitch line, when you see that sutured vaginal incision nice and closed, would have no communication with the mesh, and over the mesh would just be intact vagina that was brought back up into place. So it was just another principle 447 that we felt might help to reduce mesh exposure and complications. And we still do it to this day. I like the technique. ***	Plaintiffs have developed an incisional exposure/erosion.	*83* *Q. Are you familiar with individual physicians or centers that looked at their experience utilizing a transverse incision versus what we would call a horizontal -- vertical incision --* *A. Yes.* *Q. -- and their experience as between the two types of incisions?* *A. Well, I could tell you, for us, we've looked. It hasn't been -- it hasn't been apparent that there is an obvious risk or benefit to either. It seems that both groups do quite well.* *As far as other institutions who have formally tested one against the other, no, I'm not aware of that.* *Q. Are you aware of any literature that is compared performing an anterior apical repair comparing the use of a transverse incision as opposed to a vertical incision and the outcomes related thereto?* *A. Not -- not to my knowledge.* *rg010915, (Page 87:5 to 87:21)* *87* *you do not have an opinion that a transverse or horizontal incision in any way is necessary to reduce the risk of erosion or extrusion for the use of the Uphold mesh?* *A. Correct, but, you*

		know, as a concept, I *10 liked -- let me -- let me add, when we started the* *11 horizontal technique we liked the theoretical* *12 concept of avoiding overlap between the incision* *13 and the mesh. But in practicality, to answer your* *14 question directly, I don't believe in the end that* *15 it has a critical role or necessarily a perceptible* *16 role in reducing complication rates; and I base* *17 that on even docs that I know very well who I know* *18 are, you know, high volume and trustworthy vaginal* *19 surgeons who have had equally low complication* *20 rates using routinely a vertical incision. So, I* *21 don't think it's a critical factor.*
22 I'm going to mark as Exhibit 23 Number 832 a document that's entitled "Uphold 24 Clinical Overview." 449 1 (Deposition Exhibit Number 832 was 2 marked for identification.) 3 BY MR. KEENAN: 4 Q. If you could describe for the jury 5 what that summary exhibit represents. 6 (Document tendered to the witness.) 7 A. So this looks like it goes beyond 8 the scope of just our practice, but several of 9 these studies on here are from our division. 10 It looks like this is a 11 compilation of not only the peer-reviewed 12 publications but also some clinical posters 13 presented at meetings. 14 You know, what this I guess I'll 15 say overall because I've looked at this set of 16 studies before, one thing that stands out is it		*Counter Designation to 449:1-452:14* *rg121313, (Pages 485:10 to 488:13)* *485* *10 Q. Do you remember Exhibit 832?* *11 A. I have it right here.* *12 Q. Is this a document that you put* *13 together?* *14 A. No.* *15 Q. Who put this together?* *16 A. I saw this yesterday. This is put*

shows a great consistency in terms of the safety.

Mesh exposure is not the only important issue to talk about in terms of safety, we need to talk about pain and dyspareunia. But if you look at the mesh exposure rate, it's very low, single digits for all of these studies, and low single digits at

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our institution and elsewhere with the De Tayrac study.

Our Vu et al. study, that's Andy Vu, he's the physician that drove the analysis of this International Urogynecology Journal study in 2012. This is important for me because it represents a snapshot of every Uphold case we had ever done.

That was the goal is to get every patient in. We literally mailed out Starbucks cards until we got a nearly uniform follow-up.

These were just very satisfied patients. The mesh exposure rate at that time was 2.6 percent. With re-analysis, that may even go down. And very satisfied patients with excellent anatomic outcomes. So we continue to follow not only that cohort but the others very closely.

What's helpful with this compilation though is it shows me also in other people's hands, in surgeons' hands, and in other parts of the world, they seem to be getting a consistent result.

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There's absolutely nothing we do that is free of risk, but this shows me it's a very reasonable risk profile for a good anatomic outcome.

Q. Let's just pause for a moment and let's identify what studies then would not be reflected on this sheet, either because they are not finished or they're just beginning. So what additional studies a year from now may we have additional information about that would not be reflected in this exhibit?

A. Uphold is kind of in a unique position worldwide right now, and I think it's a great compliment to the device itself, is that it's being studied in many different arenas.

together by Mr. Keenan and team.

Q. So this is a document that the company lawyers put together and showed you?

A. Yes.

Q. Now, in this document I think Mr. Keenan asked you for the Uphold clinical studies, a listing of them; right?

A. He asked --

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Q. He asked you those questions.

A. Yes, to go through this.

Q. And this is what you testified to the jury about; right?

A. I was perusing this list and making some comments about the different studies, right. I didn't go through it in detail, obviously.

Q. Well, the first one is your group of studies, right, or your study, Goldberg et. al.?

A. Yeah, the very first one, and then the second one is a French group.

Q. The second one is Dr. de Tayrac out of Paris; right?

A. Uh-huh.

Q. And also Dr. de Tayrac out of Paris appears on the second page too; doesn't he?

A. That's right.

Q. Top of the second page.

A. Uh-huh.

At our center, for example, there's a multi-center study that actually doesn't involve me but my senior partner, Dr. Sand, along with Dr. Culligan and Dr. Rosenblatt at Harvard, they have a multi-center study of Uphold. There's an NIH-funded study. Essentially it's one of the pelvic floor 452 networks. Two major studies actually. One looking at Uphold as a comparison to a hysterectomy. Another looking at Uphold in comparison to abdominal sacral colpopexy which is another very common procedure for advanced prolapse. These are very prominent investigators, very high level studies, Level I evidence, very exciting to see it held up to that level of scientific scrutiny. And then additional studies I should say in Australia and Europe. I have no connection to those, but it's nice to see that they're ongoing.		*Q. And that's a 2011 publication involving 109 patients; right?* *487* *A. Right.* *Q. Do you know Dr. de Tayrac?* *A. I do. We've met.* *Q. You've met him or do you know him?* *A. No, we've worked together. I've met him probably four times. Actually, I was over to operate with him years ago, pre Uphold. And then we've done a workshop together here and there. So we've spent a little bit of professional time together.* *Q. So you're aware of Dr. de Tayrac's academic problems?* *A. Are you referring to -- he had the paper withdrawn or --* *Q. He had a series of papers that were withdrawn and stamped "Retracted."* *You knew about that; didn't you?* *A. You know, I don't remember the details. It was quite a long time ago. I mean I know that something happened in that regard. He's generally considered a good academician, but I knew that there was some incident that had come up.* *488* *Q. Well, do you remember in the American Journal of*

		Obstetrics & Gynecology, *3 we'll go with the American journal side of it,* *4 that there was a comment and there was a* *5 Notice of Retraction of some of his studies?* *6 A. Yes, about an IRB issue I believe.* *7 (Deposition Exhibit Number 839 was* *8 marked for identification.)* *9 BY MR. PIRTLE:* *10 Q. Right, for ethical violations;* *11 correct? (Document tendered to the witness.)* *12 A. Okay, yes. First time I've seen* *13 this.*
rg121313, (Pages 453:9 to 459:13) 17 Q. I want to hand you the Directions 18 for Use, and I want to mark it as Exhibit 833. 19 (Deposition Exhibit Number 833 was 20 marked for identification.) 21 BY MR. KEENAN: 22 Q. Do the Directions for Use tell 23 physicians they need to get trained? 24 (Document tendered to the witness.) 455 1 A. Yes. 2 Q. Exhibit 833 -- let me just to 3 expedite things. The Directions for Use state 4 that "Training on the use of the Uphold 5 Vaginal Support System is recommended and 6 available. Contact your company's sales 7 representative to arrange for this training. 8 Physicians should have experience in the 9 management of complications resulting from 10 procedures using surgical mesh." 11 You'd agree with that? 12 A. Correct. 13 Q. Okay. Give the jury some sense 14 for what kind of training you have provided 15 physicians in the field with respect to your 16 device, the Uphold? 17 A. Speaking to my involvement? 18 Q. Yes. 19 A. Well, specific to Uphold, the 20 training I've provided and my involvement with	455:13-456:10 FRE 401, 402, 403	*Counter Designation to 454:22-456:10* *rg121313, (Pages 31:8 to 32:2)* *31* *8 Getting down to brass tacks,* *9 one of the things you've done you've done* *10 preceptorships for Boston Scientific.* *11 A. "Preceptorships" meaning hosting* *12 doctors at my facility?* *13 Q. Yes, and other facilities.* *14 A. Typically at my facility, but yes.* *15 Very rare instances of going elsewhere.* *16 Q. Whereby you have trained doctors* *17 in your technique for the use of the POP* *18 device, Uphold?* *19 A. Helped with various elements of* *20 their training. Certainly not the sole source* *21 of training but helping to*

the Pelvic Floor Institute, which was a program that involved not only myself but other academic and nonacademic surgeons teaching cadaver labs, providing anatomy 456 lectures and didactics. I've also precepted doctors visiting my operating room just to look at our best practices. That's usually a fine-tuning issue, not so much for a new surgeon but somebody looking just to see the finer points of how we manage our operating room. But largely through the Pelvic Floor Institute and through weekend cadaver labs. Q. I'm going to mark as Exhibit 834 a document that I believe is from the Pelvic Floor Institute. (Deposition Exhibit Number 834 was marked for identification.) BY MR. KEENAN: Q. Can you identify this for me? (Document tendered to the witness.) A. This looks like one of the slide decks that would have been used for the didactic portion of the Pelvic Floor Institute lab. Q. There's a Table of Contents, Didactic Topics, on Page 2. Do you see that? 457 A. Yes. Q. What does this represent? A. This just represents an overview when doctors are arriving early in the morning to show them the topics that we'll be covering for that day. Q. And how long typically would the didactic go on for? A. Several hours. This was usually, my recollection, boy, probably a two- to three-hour chunk of time, depending on the number of questions and discussion. Q. There's a page here, I don't believe they're numbered, but there's a page here that has an illustration of the sacrospinous ligament. A. Okay. Q. What is that? A. Well, that's showing obviously kind of in a stripped down view of the -- it's showing a key element of the repair which is	456:10-459:11 FRE 401; 402; 403 There is no evidence the implanting physicians attended a proctored session by Roger Goldberg, MD	*distribute best* *22 practices and whatnot.* *23 Q. And you've been compensated by* *24 Boston Scientific on a per doctor basis for* *32* *1 that?* *2 A. Per hour per doctor, yes.*

the surgeon's finger here identifying what's called the ischial spine, which is a little bit of a bony landmark. And then the Capio 458 being placed adjacent to that finger. It's actually in surgical terms quite a simple technique, but this is showing the relationship between the bony anatomy and the proper placement of the suture. Q. What about managing complications, was that something that was typically addressed in the didactic? A. Typically, yes. I mean naturally, and that became obviously a bit more detailed at certain points in time. But the management of surgical complications I think even in this slide deck is going to show up at the end. So this was a typical sort of set of slides. Usually we covered this as its own unit. Q. Okay. A. Oftentimes after the actual hands-on lab, we'd go and purposefully do this over lunch so that we had time to kind of dwell on questions, finer points, how do you manage this, how do you manage that, do you use estrogen cream, things along those lines. That's where the complications were usually covered. 459 Q. And after every one of these didactics and cadaver labs, did Boston Scientific endeavor to reach out to those who attended and evaluate whether they thought the training was useful and beneficial? A. I'm assuming that was every time. I know that they would often send us e-mails just echoing positive feedback. You know, a certain percentage of patients expressing that they love the course or would recommend it to their colleagues, whatever it may be. (Deposition Exhibit Number 835 was marked for identification.)		
rg121313, (Pages 460:7 to 462:11) 460 (Deposition Exhibit Number 836 and Number 837 were marked for identification.) BY MR. KEENAN: Q. And I've marked as Exhibit 835, 836, and 837. (Documents tendered to the witness.)	460:7-461:21 FRE 401; 402; 403	

Are these examples of the results of the feedback that we received back from those that attended? And are you copied on these? A. I recall being copied on several of these, you know. It seemed to me that for the vast majority of labs they'd collect this feedback. We sort of knew doctors were getting a great experience. They'd often tell us during the labs. But it was always nice to 461 see the formal feedback in the collection of this data. Q. And based on the evaluations received from those that attended, it looks like what, the rankings were -- A. Well, for the ones that you provided, I mean it looks like close to the exceptional range, which is a good thing, in terms of the faculty, didactic, hands-on. And not to toot our own horns, because it wasn't just me, but I was never surprised by these results because it really was a very high caliber teaching module that was put together for really surgeons that came in oftentimes with a whole set of different interests and needs that day, but I felt like we could meet their needs very well. They invested a lot in the hemi-pelvis. It was a unique training environment. So I was never surprised to see the good feedback.	These exhibits and testimony are all post-implantation of Plaintiffs and have no nexus with the treating doctors in this case.	
rg121313, (Pages 462:13 to 463:8) 462 THE WITNESS: My clinical experience with polypropylene has been, again, I'm privileged that I've been able to operate in the era of using these Type I polypropylene mesh products, because I know that other implants, like Goretex and whatnot, were less well tolerated in years past. But I've just simply never had a material problem with polypropylene, period. And I tell patients that, you know, I've now done these in the thousands when you talk about slings, for example, I have 463 literally never seen an infection or rejection,	462:9-463:8 FRE 401; 402; 403; 701; and 702 These opinions have been found unreliable under *Daubert.*	

some kind of a delayed strange material complication, inflammation, ever, not once. Complications, of course, are inherent to anything we do. But on a material level, absolutely no concerns recommending it to my patients, to my wife, to my mother, clinically based on what I know as a surgeon		
rg121313, (Pages 463:15 to 464:11) 463 Q. But have you ever seen any evidence, clinical evidence, of mesh shrinkage, for example? A. I truly have not. I know that that's been a point of discussion, and I have my -- I think that, you know, I have my clinical clinical experience to indicate that I've just never seen that happen. I think there's certainly a fibrous scar that forms around any surgery. 464 That's the nature of surgical scar even probably with native tissue. So if there's any contraction or scar deposition, that may be plausible as a reason why things can contract slightly. But I've just never seen that clinically with this technique. Q. What about degradation or degrading of the mesh, have you ever seen that clinically? A. No.	463:15-464:11 FRE 401; 402; 403; 701; and 702 These opinions have been found unreliable under *Daubert.* .	
rg121313, (Pages 473:19 to 476:4) *** Q. Today what are the sources of information for physicians about the risks and benefits of the Uphold or similar products using transvaginal mesh? A. Well, it's pervasive. I mean on the level of literature, you know, society, guideline statements, opinion papers, continuing medical education. Industry is a slice of that pie but actually a very small slice. 476 The doctor who chooses to adopt this into his or her practice, you know, really has all tiers to get that sort of training or expertise.	475:15-476:1 FRE 401, 402, 403	

1. **Objections to BSC Exhibits**

   a. Plaintiffs object to Goldberg 827 under FRE 403 as it appears to be an Uphold Light device.

   b. Plaintiffs object to Goldberg 829 under FRE 403 as the device treats a form of prolapse not at issue in this case. The jury will be misled by the comparison of the Uphold to the Prolift Total.

   c. Plaintiffs object to Goldberg 834 under FRE 401 and 403 as there is no evidence Plaintiffs implanting physicians attended an event proctored by Dr. Goldberg.

   d. Plaintiffs object to Goldberg 835; 836; and 837 under FRE 401, 402, and 403, as the exhibits and testimony have no discernable nexus with the treating physicians in these cases. Additionally, these Exhibits are post-implantation.

2. **Counter Exhibits**

   a. Goldberg Exhibit 840
   b. Goldberg Exhibit 839

DATED: June 26, 2015

Respectfully Submitted,

TRACEY & FOX LAW FIRM

/s/ Sean Tracey
Sean Patrick Tracey
State Bar No. 20176500
Shawn P. Fox
State Bar No. 24040926
Clint Casperson
State Bar No. 24075561
440 Louisiana, Suite 1901
Houston, TX 77002
(800) 925-7216
(866) 709-2333
stracey@traceylawfirm.com
sfox@traceylawfirm.com
ccasperson@traceylawfirm.com

/s/ *John R. Fabry*
John R. Fabry
Texas Bar No. 06768480
Mark R. Mueller
Texas Bar No. 14623500
MUELLER LAW, PLLC
404 West 7th Street
Austin, TX 78701
(512) 478-1236
(512) 478-1473 (Facsimile)
John.Fabry@muellerlaw.com
Mark@muellerlaw.com

Meshservice@muellerlaw.com

CERTIFICATE OF SERVICE

I hereby certify that on June 26, 2015, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

TRACEY & FOX LAW FIRM

/s/ Sean Tracey
Sean Patrick Tracey
State Bar No. 2176500
Shawn P. Fox
Clint Casperson
State Bar No. 24075561
State Bar No. 24040926
440 Louisiana, Suite 1901
Houston, TX 77002
(800) 925-7216
(866) 709-2333
stracey@traceylawfirm.com
sfox@traceylawfirm.com
ccasperson@traceylawfirm.com

/s/ *John R. Fabry*
John R. Fabry
Texas Bar No. 06768480
Mark R. Mueller
Texas Bar No. 14623500
MUELLER LAW, PLLC
404 West 7th Street
Austin, TX 78701
(512) 478-1236
(512) 478-1473 (Facsimile)
John.Fabry@muellerlaw.com
Mark@muellerlaw.com
Meshservice@muellerlaw.com